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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,457	11/13/2000	ANTONI BANAS	P04962US/UA/MW	4182

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/709,457

Applicant(s)

BANAS ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-9 are cancelled and newly added Claims 16-27 are examined.

#### ***Claim Objections***

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The Claim is dependent upon itself. However, interpreting the claim to recite "The transgenic plant according to Claim 22 selected from agricultural plants" fails to further limit the oil seed crops of Claim 22.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a nucleic acid sequence encoding an enzyme catalyzing the transfer of a fatty acid from acyl-CoA to diacylglycerol for the production of triacylglycerol, wherein said nucleic acid sequence is derived from SEQ ID NO: 1 or the *Saccharomyces cerevisiae ARE1* gene.

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Applicant describes the nucleic acid of SEQ ID NO: 1 encoding the amino acid of SEQ ID NO: 2.

Applicant does not describe sequences derived from SEQ ID NO: 1 or the *Saccharomyces cerevisiae ARE1* gene, or sequences which encode protein other than SEQ ID NO: 2.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Applicant asserts that the amendments to the claims overcome the rejection (response pages 6-7). The amendments do not remedy the problems as discussed above.

Claim 16-18 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increases in TAG levels in *Brassica* family plants (*Arabidopsis* and *Brassica napus*) and yeast transformed with SEQ ID NO: 1, does not

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reasonably provide enablement for any increase in oil content in an <sup>y</sup>oil producing plant or oil producing organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a nucleic acid sequence encoding an enzyme catalyzing the transfer of a fatty acid from acyl-CoA to diacylglycerol for the production of triacylglycerol, wherein said nucleic acid sequence is derived from SEQ ID NO: 1 or the *Saccharomyces cerevisiae ARE1* gene; methods of using said sequences to increase the oil content in any oil producing plant.

Applicant teaches disruption of the ARE1 gene in yeast and a reduced accumulation of TAG by 40% when compared to wild type yeast (Example 1 pages 6-9); yeast transformed with and overexpressing the ARE1 gene having increased TAG levels (Example 2 pages 9-10); diacylglycerol acyltransferase activity, measured as radiolabelled TAG production, in microsomal fractions prepared from wild type and mutant (*arel*) yeast cells transformed with a plasmid encoding ARE1 (Example 3 pages 11-12); *Arabidopsis* transformed with and expressing the ARE1 gene from yeast having increased TAG levels and increased fatty acid levels per weight seed (Example 4 pages 13-14); and increased TAG levels in *Brassica napus* transformed with SEQ ID NO: 1.

Applicant does not teach increased oil content in plants transformed with SEQ ID NO: 1 other than *Arabidopsis*, or in organisms other than yeast.

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Given the lack of guidance for producing plants to have increased oil content in the specification; that reflect the breadth of the claims, and given the unpredictability in the art, undue trial and error experimentation would be needed by one skilled in the art to alter the phenotype of a multitude of oil producing plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

Applicant asserts the present amendments obviate the Examiner's allegation that the specification does not provide enablement for any organism transformed with any nucleotide sequence encoding an amino acid that catalyzes the transfer of a fatty acid from acyl-CoA to diacylglycerol to produce TAG and that the claimed invention would only be enabled by trial and error experimentation (response page 7). The amendments do not overcome the rejection as stated above.

*experimentation*

Applicant further asserts that the test for enablement is not whether <sup>^</sup>is necessary but whether the experimentation is undue, asserting that the present disclosure would only require routine experimentation, and state <sup>s</sup>that evidence of this assertion is in Applicant's declaration by Dr. Oliver Oswald where *Brasica napus* overexpressing the ARE1 gene exhibit <sup>s</sup>a significant increase in oil content, thus demonstrating enablement for species beyond *Arabidopsis* and yeast (response pages 7-8). The declaration does not show an increase in the oil content of seeds as Applicant contends, but rather shows that there is an increase in TAG content with no indication of what the levels of total oil are with respect to seed weight seed as shown in *Arabidopsis* on pages 13-14 of the specification. Applicant has not enabled the invention for the full breadth of the claims as discussed above. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not

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constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in the rejection.

Claims 16, 26, and 27, drawn to a method of increasing the oil content in either an oil producing plant or organism, are indefinite because the claims fail to recite in the body of the claim that the oil content of said organisms have been increased. Appropriate correction is required.

At Claim 19, line 4, “is derived from” is indefinite. It is unclear how the sequence is to be derived and what has changed from the original sequence.

At Claim 20, line 2, “encodes for enzyme” is grammatically incorrect. Changing the claim to recite --encodes an enzyme-- would obviate this rejection.

Applicant asserts that “derived from” is no longer recited in the claims (response page 9). See 112 2<sup>nd</sup> paragraph rejection of Claim 19 above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 19 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lardizabal K. *et al.*, WO 98/55631A1 published December, 10 1998, as stated for Claims 1-9 in the last office action.

The claims are indefinite as discussed supra, specifically nucleic acid sequences “derived from” SEQ ID NO: 1 or the ARE1 gene from yeast read upon any other nucleic acid sequences having diacylglycerol acyltransferase activity.

Lardizabal teaches that flux into glycerol lipids is controlled by diacylglycerol acyltransferase converting DAG into TAG and its usefulness in increasing oil production in a plant on page 3 line 22 to page 4 line 24; agricultural plants useful for increasing oil production in a plant transformed with a nucleic acid sequence encoding an amino acid expressing a diacylglycerol acyltransferase on page 22 lines 14 to 36; techniques useful for isolating diacylglycerol acyltransferase (DAGAT) genes; and the usefulness of seed specific napin and oleosin promoters for increasing oil production in seeds. Thus the reference teaches all the limitations of Claims 19 and 21-25.

Applicant asserts that the Lardizabal reference fails to disclose or suggest the nucleotide and/or amino acid sequences of the present invention and thus fails to anticipate the claimed invention (response page 9-10). Applicant’s claim to sequences “derived from” in Claim 19 is indefinite as discussed above.

Claims 16-18 and <sup>20</sup>~~26~~<sub>27</sub> are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1 and isolated polynucleotides encoding SEQ ID NO: 2 and *Brassica* family plants transformed with said polynucleotides.



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Claims 16-27 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

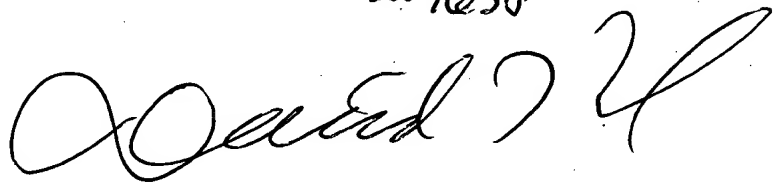
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.  
August 10, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180/1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.